

Serial Number: TBD
Attorney Docket: SPEI3003/ESS

LISTING AND AMENDMENT OF THE CLAIMS:

1. (Canceled).
2. (Currently amended) ~~Use as claimed in Claim 1~~ The process of Claim 40 wherein the water is used admixed in step (a) in an amount of between from about 180 wt % to about 190 wt % of the component composition.
3. (Canceled).
4. (Currently amended) ~~Use as claimed in any of Claims 1 to 3~~ The process of Claim 40 wherein between from about 80 % to about 98 % of particles produced in step (d) have a diameter between the range of about 800 to about 1500 μm .
5. (Canceled).
6. (Currently amended) ~~Use as claimed in Claim 3~~ The process of Claim 2 wherein use of 5 wt % more water increases particle size such that the water is admixed in an amount of about 190 wt % of the component composition and substantially all of the particles have a diameter over 1500 μm .

Serial Number: TBD
Attorney Docket: SPEI3003/ESS

7. (Currently amended) ~~Use as claimed in any of the preceding claims~~
The process of Claim 40 wherein the dry particles produced in step (d) are
screened to obtain particles having a diameter with the range of about 800 to
about 1500 μm .

8. (Currently amended) ~~Use as claimed in any of the preceding claims~~
The process of Claim 40 wherein the component composition of step (a)
~~composition~~ further comprises a therapeutically effective amount of active
compound selected from the group consisting of peptides, polypeptides,
proteins, interferons, TNF antagonists, protein and peptide agonists and
antagonists of the immune system, hormones, cytokines and cytokine
agonists and antagonists, analgesics, antipyretics, antibacterial and
antiprotozoal agents, anti-infective agents, antibiotics, antiviral agents,
antifungal agents, antimalarial agents, anti-inflammatory agents, steroids,
probiotics and prebiotics, opiate agonists and antagonists, bisphosphonates,
anticancer and cytotoxic agents, immunomodulators, antiparasitic agents and
pharmacologically acceptable salts and derivatives of each of these ~~actives~~
active compounds.

9. (Currently amended) ~~Use as claimed in any of the preceding claims~~
The process of Claim 40 wherein the component composition of step (a)
~~composition~~ further comprises a therapeutically effective amount of active
compound selected from the group consisting of erythropoietin, human growth

Serial Number: TBD
Attorney Docket: SPEI3003/ESS

hormone, metronidazole, albenazole, mebendazole, praziquantel, clarithromycin, gentamycin, ciprofloxacin, rifabutin, 5-aminosalicylic acid, 4-aminosalicylic acid, balsalazide, prednisolone metasulphobenzoate, α -amylase, paracetamol, metformin, cyclophosphamide, cisplatin, vincristine, methotrexate, azathioprine and cyclosporin ~~or~~ and pharmacologically acceptable salts or derivatives thereof.

10. (Currently amended) ~~Use as claimed in Claim 9 or Claim 10~~ The process of Claim 40 wherein the component composition of step (a) further comprises a therapeutically effective amount of active compound is prednisolone or a pharmacologically acceptable salt or derivative thereof.

11. (Currently amended) ~~Use as claimed in Claim 9 or Claim 10~~ The process of Claim 40 wherein the component composition of step (a) further comprises a therapeutically effective amount of active compound is metronidazole or a pharmacologically acceptable salt or derivative thereof.

12. (Currently amended) ~~Use as claimed in Claim 9 or Claim 10~~ The process of Claim 40 wherein the component composition of step (a) also comprises a therapeutically active compound ~~is effective amount of~~ erythropoietin or a pharmacologically acceptable salt or derivative thereof.

13. (Canceled).

Serial Number: TBD
Attorney Docket: SPEI3003/ESS

14. (Currently amended) ~~Use as claimed in any of Claim 8 to 13~~ The process of Claim 8 wherein the ~~therapeutically~~ active compound is present in an amount between from more than 0 wt % to about 90 wt% of the component composition.

15. – 17. (Canceled).

18. (Currently amended) ~~Use as claimed in any of the preceding claims~~ The process of Claim 40 wherein the rheology modifying agent comprises croscarmellose sodium.

19. (Canceled).

20. (Currently amended) ~~Use as claimed in any of the preceding claims~~ The process of Claim 40 wherein the rheology modifying agent is present in the component composition of step (a) in an amount of at least 5 wt % of the said component composition.

21. – 23. (Canceled).

24. (Currently amended) ~~Use as claimed in any of the preceding claims~~ The process of Claim 40 wherein the component composition of step (a) further comprises a sugar.

Serial Number: TBD
Attorney Docket: SPEI3003/ESS

25. (Currently amended) ~~Use as claimed in~~ The process as claimed in Claim 24 wherein the sugar is lactose monohydrate.

26. (Currently amended) ~~Use as claimed in Claim 24 or Claim 25~~ The process as claimed in Claim 24 wherein the sugar is present in an amount of between from about 30 to about 50 wt % of the component composition.

27. (Canceled).

28. (Currently amended) ~~Use as claimed in any of the preceding claims~~ The process of Claim 40 wherein the component composition of step (a) further comprises a cellulose.

29. (Currently amended) ~~Use as claimed in Claim 28~~ The process of Claim 28 wherein the cellulose is microcrystalline cellulose.

30. (Currently amended) ~~Use as claimed in Claim 28 or Claim 29~~ The process of Claim 28 wherein the cellulose is present in an amount of between from about 35 to about 45 wt % of the component composition.

31. (Canceled).

32. (Currently amended) ~~Use as claimed in any of the preceding claims~~

Serial Number: TBD
Attorney Docket: SPEI3003/ESS

The process of Claim 40 wherein the component composition of step (a) consists essentially of prednisolone or a pharmacologically acceptable salt or derivative thereof, a rheology modifying agent, sugar and cellulose.

33. (Currently amended) ~~Use as claimed in any of Claims 1 to 31~~ The process of Claim 40 wherein the component composition of step (a) consists essentially of metronidazole or a pharmacologically acceptable salt or derivative thereof, a rheology modifying agent, sugar and cellulose.

34. (Currently amended) ~~Use as claimed in any of Claims 1 to 31~~ The process of Claim 40 wherein the component composition of step (a) consists essentially of erythropoietin or a pharmacologically acceptable salt or derivative thereof, a rheology modifying agent, sugar and cellulose.

35. (Canceled).

36. (Currently amended) A process for the production of particles for use in a pharmaceutical composition, said process comprising the steps of:

mixing water with a component composition comprising at least a rheology modifying agent to produce a paste;

extruding at least a portion of the paste to form extrudate;

spheronizing at least a portion of the extrudate to form spheronized particles; and

Serial Number: TBD
Attorney Docket: SPEI3003/ESS

drying at least a portion of the spheronized particles-, the amount of water admixed in the mixing step being between from about 180 to 190 wt % of the weight of the component composition and, where the spheronizing step uses a 70 cm plate rotating at 200 to 1000 rpm.

37. – 39. (Canceled).

40. (New) A process for producing particles of controlled size and size distribution for use in a pharmaceutical composition, comprising the steps of

(a) admixing water with a component composition to produce a paste, the water being admixed in an amount effective to provide in step (d) spheronized particles of controlled particle size and size distribution, the component composition comprising at least a rheology modifying agent in an amount effective to form on hydration a matrix with visco-elastic property,

(b) extruding at least a portion of the paste to form extrudate,

(c) spheronizing at least a portion of the extrudate to form spheronized particles; and

(d) drying at least a portion of the spheronized particles.

41. (New) The process of Claim 9 where the active compound is present in an amount between from more than 0 wt % to about 90 wt % percent of the component composition.